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| ARENT FOX LLP 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036 | | | | |
| EXAMINER | | | | |
| JOKE, MICHELE K | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1636 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com
IPMatters@arentfox.com
Patent_Mail@arentfox.com

Office Action Summary

Application No.

10/519,404

Applicant(s)

PARKER ET AL.

Examiner

MICHELE K. JOIKE

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6 is/are rejected.
- 7) ☒ Claim(s) 7-15 and 17-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date 1/4/05
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on April 24, 2008 is acknowledged. The traversal is on the ground(s) that there that search burden is less than it is for the Applicant. This is not found persuasive because unity of invention was broken as discussed in the prior office action.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 24, 2008.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on April 7, 2002. It is noted, however, that applicant has not filed a certified copy of the 0215496.1 application as required by 35 U.S.C. 119(b).

Claim Objections

Claims 7-15 and 17-21 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other

multiple dependent claims. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete method claims. Claims 1 and 2 are incomplete for omitting essential steps. While all of the technical details of a method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is to be practiced. The only recited step is for assessing inhibition. It is unclear how the assessment is performed. How is it determined whether the compound inhibits?

Although claims 3 and 4 are dependent on claim 1, they are not included in the rejection because they claim complete methods.

Claim 6 is unclear because the promoter is linked to its natural reporter gene, which is unclear because of what is taught by the specification. It is confusing, because the specification, in paragraphs 35 and 36, teaches that "[g]enes that are linked to an SF-1 regulated promoter in nature from which the SF-1 regulated promoter may be derived include aromatase, lutenising hormone beta, follicle stimulating hormone, StAR,

cholesterol side-chain cleavage enzyme, DAX-1, anti-mullerian hormone, kallikrein and RLF (see Kosikimies et al, 2002, Endocrinology 143(3): 909-919)". However, use of the word "link" and "nature" and the language of claim 6 would appear to limit the promoter to be linked to its own gene. There is no indication that the word "link" means regulate. If claim 6 is dependent on claim 4, then the SF-1 promoter would be linked to the SF-1 gene. However, the specification would appear to teach that any gene regulated by SF-1 could be used, so it is confusing as to whether the SF-1 gene is the reporter, or whether any gene regulated by SF-1 is the reporter. Also, the language appears to indicate that the promoter can be derived from another gene. Therefore, if this is the case, deriving a promoter can cause modifications that no longer make it natural, so it is unclear what reporter gene would be used. The specification fails to clearly define the language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mellgren et al in view of US 5,525,490.

Mellgren et al (IDS reference AN, especially pp. 91-93, 101) teach that SF-1 interacts with RIP140 (Nrip1). Yeast two-hybrid assays were performed to determine this interaction, using a lacZ reporter. β -galactosidase assays measured the strength of the interaction. It was also determined that it was possible to inhibit RIP140 interaction with SF-1 by application of Trichostatin A. However, they do not teach a method of screening for inhibitors.

US 5,525,490 (col. 1-7) teaches a reverse two-hybrid method designed for screening for molecules that can inhibit protein-protein interactions.

The ordinary skilled artisan, desiring to use a screening method for inhibitors of SF-1/RIP140, would have been motivated to combine the teachings of Mellgren et al teaching that SF-1 interacts with RIP140 and that it was possible to inhibit RIP140 interaction with SF-1 by application of Trichostatin A with the teachings of US 5,525,490 teaching a reverse two-hybrid method designed for screening for molecules that can inhibit protein-protein interactions because US 5,525,490 taught that there is a need in the art for compositions and methods which can be used to efficiently identify agents that specifically alter the intermolecular association between two polypeptide

sequences, and could be used for drug discovery. It would have been obvious to one of ordinary skill in the art to use the screening method taught by US 5,525,490 to screen for inhibitors of SF-1/RIP140, since it is desirable to find inhibitors of SF-1 and RIP140, as these proteins are pharmaceutically important and known to interact, and Mellgren et al teach that SF-1 is pivotal in adrenal development and sexual differentiation, and that RIP140 is a coactivator of the estrogen receptor in breast cancer cells. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE K. JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K Joiike/
Examiner, Art Unit 1636

Michele K Joiike
Examiner
Art Unit 1636